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Nicotine application with an oral capsule

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An elastic gelatin capsule has been developed which releases 4 mg of nicotine in 0.8 ml of an alkaline solution (pH 10) into the mouth after crunching the capsule's wall. In a pilot study with 5 male smokers and 5 male nonsmokers, nicotine absorption after administration of one capsule was studied by measuring the alkaloid and its main metabolite, cotinine, in plasma and urine. Cardiovascular responses were recorded before, during and after administration of a verum and a placebo capsule. In addition, the subjects were enquired how they felt after administration of the capsule. The peak nicotine concentration in plasma was reached 10 min after application of the nicotine capsule and ranged from 4 to 10 ng/ml. In those subjects who were advised to swallow the contents of the capsule instead of spitting it out after 4 min, a second nicotine peak was observed 40 to 120 min after administration. In most of the subjects nicotine uptake through the capsule was accompanied by an increase in heart rate and systolic blood pressure and a decrease in skin temperature. Subjective response to and tolerance of the nicotine capsule varied from subject to subject. There was no significant difference between smokers and nonsmokers in any of the variables measured.

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